REMARKS

Applicant requests reconsideration of the pending claims in this application in view of the foregoing amendments and the following remarks.

Status of Claims

Claims 73, 90, 93-96, 99, 101, 105-109, 117-121 are currently pending, with claims 73, 90, 93, 95, 101, 105, 106 and 108 being independent. Claims 1-72, 74, 76-79, 82-89, 91-92, 97-98, 100, 102-104 and 110-116 have previously been cancelled, without prejudice to or disclaimer of the subject matter recited therein. Claims 75, 80 and 81 have been cancelled in this Amendment, without prejudice to or disclaimer of the subject matter recited therein. Claims 73, 90, 93, 95, 99, 101, 105, 106 and 108 are currently amended to place them in better form for allowance. No new matter has been added by these amendments. Claims 93-96, 106-109, 119 and 120 are allowed.

Statement of Substance of Interview

At the outset, Applicant would like to thank the Examiner for the courtesies extended in granting and conducting an interview in the present application.

Potential claim amendments were discussed at the interview to place the pending claims in better form under U.S. practice. Moreover, the claims were discussed in the context of the cited documents. At the interview, Applicant explained that U.S. Patent No. 5,731,319 to Aberg et al. does not teach a composition comprising desloratadine in a free base form together with a pharmaceutically acceptable antioxidant, wherein the desloratadine does not form a pharmaceutically acceptable salt with the antioxidant. As discussed at the interview, the cited documents, taken alone or in combination, do not teach additional features of the claimed invention, such as: (1) the total amount of desloratadine degradation products in the solid composition; (2) a specific dissolution rate for desloratadine; and (3) a specified amount of antioxidant.

Obviousness Rejections

Claims 73, 75, 80, 81, 90, 99, 101, 105, 117, 118 and 121 have been rejected under 35 USC 103(a) as being unpatentable over the Aberg et al. patent in view of U.S. Patent No. 6,372,802 to Hellberg et al. Applicant traverses this rejection and requests that such rejections be withdrawn in view of the foregoing amendments and these remarks.

Further to the Examiner's suggestions during the Interview, claims 73, 90, 101 and 105 have been amended to incorporate the features of previously-pending claims 75, 80 and 81, such as: (1) the total amount of desloratadine degradation products in the solid composition; (2) a specific dissolution rate for desloratadine; and (3) a specified amount of antioxidant. Moreover, claims 73, 90, 101 and 105 now clarify that the free base form desloratadine in the solid composition does not form a pharmaceutically acceptable salt with the antioxidant in the composition.

Claim 73 now recites a solid composition comprising an anti-allergic effective amount of desloratadine in a free base form and a desloratadine-protective amount of at least one pharmaceutically acceptable antioxidant, wherein: the desloratadine does not form a pharmaceutically acceptable salt with the antioxidant; about 0.1% to about 10% of the at least one pharmaceutically acceptable antioxidant is present; at least 80% of the desloratadine dissolves in a 0.1N HCl solution at 37° C in about 45 minutes; and the total amount of desloratadine degradation products in the solid composition is less than or equal to 2% by weight.

Claim 90 additionally specifies a dosage of 5 mg for desloratadine. Claim 90 recites a solid composition comprising about 5 mg of desloratadine in a free base form and a desloratadine-protective amount of at least one pharmaceutically acceptable antioxidant, wherein: the desloratadine does not form a pharmaceutically acceptable salt with the antioxidant; about 0.1% to about 10% of the at least one pharmaceutically acceptable antioxidant is present; at least 80% of the desloratadine dissolves in a 0.1N HCl solution at 37° C in about 45 minutes; and the total amount of desloratadine degradation products in the solid composition is less than or equal to 2% by weight.

Claim 101 recites a solid composition comprising an anti-allergic effective amount of desloratadine in a free base form and a desloratadine-protective amount of two pharmaceutically acceptable antioxidants, wherein the two pharmaceutically acceptable antioxidants are edetate

disodium and citric acid, and wherein: the desloratadine does not form a pharmaceutically acceptable salt with the antioxidant; about 0.1% to about 10% of the two pharmaceutically acceptable antioxidants is present; at least 80% of the desloratadine dissolves in a 0.1N HCl solution at 37° C in about 45 minutes; and the total amount of desloratadine degradation products in the solid composition is less than or equal to 2% by weight.

Finally, claim 105 recites a solid composition comprising about 2.5 mg desloratadine in a free base form and a desloratadine-protective amount of at least one pharmaceutically acceptable antioxidant, wherein: the desloratadine does not form a pharmaceutically acceptable salt with the antioxidant; about 0.1% to about 10% of the at least one pharmaceutically acceptable antioxidant is present; at least 80% of the desloratadine dissolves in a 0.1N HCl solution at 37° C in about 45 minutes; and the total amount of desloratadine degradation products in the solid composition is less than or equal to 2% by weight.

Accordingly, Applicant submits that its claimed invention is patentable over both the Aberg et al. patent and the Hellberg et al. patent, taken together or separately. Aberg et al. teaches away from what would be considered a "pharmaceutically acceptable antioxidant" as contemplated by Applicant's claimed invention by noting that carboxylic classes of organic acids, such as stearic acid, are suitable organic acids that could be used to formulate a "pharmaceutically acceptable salt." Applicant's specification indicates that organic acids such as stearic acid, povidone and crospovidone as well as the hydroxycarboxylic acid, ascorbic acid, cause discoloration and instability of desloratadine and so could not be considered "pharmaceutically acceptable antioxidants" (i.e., see para. [0028] of US 2004/0097536 A1). Applicant notes that neither Aberg et al. nor Hellberg et al. explicitly teaches citric acid.

In view of the above, Applicant submits that the remaining rejected claims are in condition for allowance in addition to those already identified in the Office Action as being allowed. Applicant further requests reconsideration and withdrawal of the outstanding rejections. Applicant requests the Examiner to contact Applicant's undersigned representative should there be any remaining issues precluding allowance of this application.

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Respectfully submitted,

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